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**QUALITY ASSURANCE PROGRAM GUIDELINES
FOR
APPLICATION TO AND USE BY MANUFACTURERS
OF
RAIL/GUIDEWAY VEHICLES, BUSES,
AUTOMATIC TRAIN CONTROL SYSTEMS,
AND THEIR MAJOR SUBSYSTEMS**

(NASA-CR-149558) QUALITY ASSURANCE PROGRAM
GUIDELINES FOR APPLICATION TO AND USE BY
MANUFACTURERS OF RAIL/GUIDEWAY VEHICLES,
BUSES, AUTOMATIC TRAIN CONTROL SYSTEMS, AND
THEIR MAJOR SUBSYSTEMS (Jet Propulsion Lab.) G3/85

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1.0 INTRODUCTION

1.1 SCOPE

This document describes guidelines for a Quality Assurance system that is applicable to and for use by, manufacturers of:

- Rail/Guideway vehicles
- Buses
- Automatic Train Control Systems (ATC)
- Major subsystems or critical components

that are being procured for use in Public Urban Mass Transit Systems.

These guidelines are to be implemented by the manufacturer in support of designing, developing, fabricating, assembling, inspecting, testing, handling and delivery of the foregoing equipment.

The guidelines apply to this equipment when being procured for:

- (a) Use in Revenue Service
- (b) Demonstration Programs of systems that will be "Revenue Producing" or "used by the public"
- (c) Use as a Prototype for follow-on operational/Revenue Producing Equipment procurements
- (d) "Qualification" tests

When on-site (property) installation, and/or preoperational checkout phases of rail/guideway/ATC equipment are part of the contract, the appropriate control and verification elements of the guideline shall be applied.

The degree of detail implementation of any item in the guideline will vary with the maturity of the manufacturer, the design, and the type and quantity of items being manufactured.

1.2 PURPOSE

The purpose of this quality assurance system is to establish a systematic approach to ensure that the contracted and desired product is produced in a timely and cost-effective manner. It emphasizes preventive as well as verification activities and functions. It requires that adequate and proper design definition be made; that procured items be controlled; that fabrication and assembly activities be defined and controlled; and it provides verification functions and activities to validate that what is produced is what was contracted for.

These requirements are specified in a manner intended to protect the interests and needs of both transit system buyers and producers. The intended response and execution of these requirements will promote delivery of safe, reliable, economical, and maintainable vehicles by enabling producers to use proven practices in an economical manner.

1.3 PRODUCER-BUYER INTERFACES

The quality assurance program of the manufacturer, including his subcontractors, is subject to evaluation by the customer during the contract period. Hardware produced or being produced is subject to inspection and test by the buyer at the producer's plant. The producer shall provide buyer access to the plant and work operations. Applicable producer documents, records and inspection/test equipment shall be made available to authorized buyer representatives in the plant and at the work station where the work is being verified. Producer personnel shall be made available when necessary to assist in the operation of inspection and test functions being verified.

The buyer shall give consideration to the producer in establishing and implementing in-series functions or activities, e.g., inspection, testing, approvals, acceptance, etc. so that schedules are not unduly jeopardized.

The buyer and seller will mutually identify all documents and actions requiring buyer approval, concurrence, and review.

The seller shall make proviso for access and will coordinate visits to his vendors when such a visit is requested by the buyer.

Documents and records shall be made available and provided to the buyer for his in-plant use.

The contract should specify what documents and records, in addition to the following, are to be formally "delivered" to the buyer. Where the contract is silent, the following shall be submitted as a minimum:

- (a) Acceptance inspection and test records
- (b) Acceptance test procedures
- (c) Waiver requests
- (d) Documentation requiring customer approval, concurrence, or review
- (e) Failure Reports
- (f) Customer signed nonconformance documents
- (g) Chart(s) showing flow of fabrication, assembly inspection, and test operations
- (h) Quality Plan (Rail/Guideway vehicles and ATC systems)
- (i) Quality Manual (policy and procedures)
- (j) All changes to the foregoing documents

1.4 PRODUCER'S RESPONSIBILITY

The producer is responsible for the quality of the products developed or delivered and to provide real evidence that quality requirements are fulfilled. This responsibility is not reduced or relieved by buyer inspection or evaluation.

1.5 DOCUMENTS

Policies, practices and procedures for quality assurance and interfacing functions to be performed shall be defined and prescribed in appropriate management and other documents. These

documents shall evidence recognition of quality requirements and a planned organized approach to achieve them. The producer shall prepare and maintain an index of documents and an organization chart showing key organizations, their functional responsibilities, and the person in charge.

1.6 DOCUMENT CONTROLS

The producer shall control the release and distribution of documents to ensure that:

- (a) Documents are reviewed by authorized personnel prior to use.
- (b) Only the latest, correct and applicable documents reach using organizations (e.g., design, purchasing, fabrication or inspection), and are available at work stations.
- (c) Superseded or replaced documents are removed in a timely manner. Documents used for production should have an expiration date and require revalidation of use or be replaced or by an equivalent control method.
- (d) Changes and revisions are controlled to the same degree as the original.
- (e) Replacement parts can be provided over the period specified in the contract and such replacements are interchangeable with those manufactured at an earlier date or period.
- (f) Work operations involving a mix of documents having various revision letters or dash numbers can be performed simultaneously.

Controls over documents shall be compatible with other internal management systems and with the quality program.

2.0 QUALITY PROGRAM

The producer shall be responsible for establishing and operating a cost-effective quality program in response to these requirements and tailored to the nature of the hardware he produces and to other requirements of the contract, including applicable regulations, codes, standards and specifications. The quality program shall be so designed and implemented as to incorporate existing effective procedures and practices which satisfy these guidelines. The producer is not expected to create new procedures and practices for each element of the guideline, but, he is expected to revise existing procedures and practices, if needed, to meet these guidelines.

2.1 RELATION TO OTHER REQUIREMENTS

The quality program shall satisfy the quality assurance guidelines contained herein, in addition, to those of other applicable regulations, codes, standards and specifications. Overlapping and interfacing requirements (such as system safety, reliability, maintainability and test) defined or established for the contract, shall not result in duplicate efforts. The quality program shall be integrated into producer operations in a manner consistent with his operational and management practices for design, development, purchase, fabrication, assembly, test, storage, shipment, on-site installation and operational checkout.

2.2 QUALITY PROGRAM PLAN (RAIL, GUIDEWAY VEHICLES AND AUTOMATIC TRAIN CONTROL SYSTEM)

The producer shall prepare a written quality program plan describing how he will comply with each element of the guideline, and how the quality assurance effort will be planned and adjusted to each phase of the work. The format of the plan shall readily identify producer quality program functions and responsibilities for each element. The plan shall be submitted for approval prior to the bid submittal and any subsequent change approved prior to implementation.

Applicable producer policies and procedures shall be referenced in the plan. Provisions shall be made for generation, revision and review or approval of documents as the work progresses. Chart(s) showing the flow of fabrication and assembly operations with related inspection and test points shall be included in the plan as they are generated. The quality plan shall contain separate sections to define and provide for activities at the producer's facility, at an associate contractor's (e.g., ATC at vehicle manufacturer) facility, and at the transit system site (rail or guideway and ATC).

3.0 ORGANIZATION AND MANAGEMENT

3.1 ORGANIZATION

Organizational responsibilities and inter-relationships necessary to define and implement each quality program function shall be described in the producer's policies, procedures and instructions. Persons performing quality program functions shall have sufficient authority, responsibility and organizational freedom to identify and evaluate quality deficiencies and to initiate corrective actions. Inspection and acceptance shall be made by persons independent of the organization doing the work. There are many approaches to organizational and management structure. This guideline does not specify a particular approach. However, there are some that preclude the necessary independence of auditing and validating functions. Figures 1 and 2 show typical structures that are acceptable and nonacceptable (respectively).

Under controls established for the quality program, work may be inspected by the operator or "doing" organization prior to inspection/acceptance by quality assurance (e.g., manual operations, such as soldering, welding or brazing, where operator skill controls the quality of product).

3.2 MANAGEMENT

An individual shall be assigned the responsibility for coordinating these requirements with all affected organizational elements, and assuring their establishment, implementation, and accomplishment. The producer's management structure shall ensure that interfacing activities, such as design, reliability, system safety, purchase, fabrication, assembly, test, on-site installation and checkout, storage and shipment provide inputs or support necessary to economic achievement of quality program functions.

3.3 PERSONNEL QUALIFICATION

The producer shall have trained and competent personnel to implement the quality program. Training activities and work supervision shall emphasize:

- Excellence of workmanship and personnel skills
- Careful and safe operations
- Maintenance and improvement of product quality
- Early detection of causes of poor quality

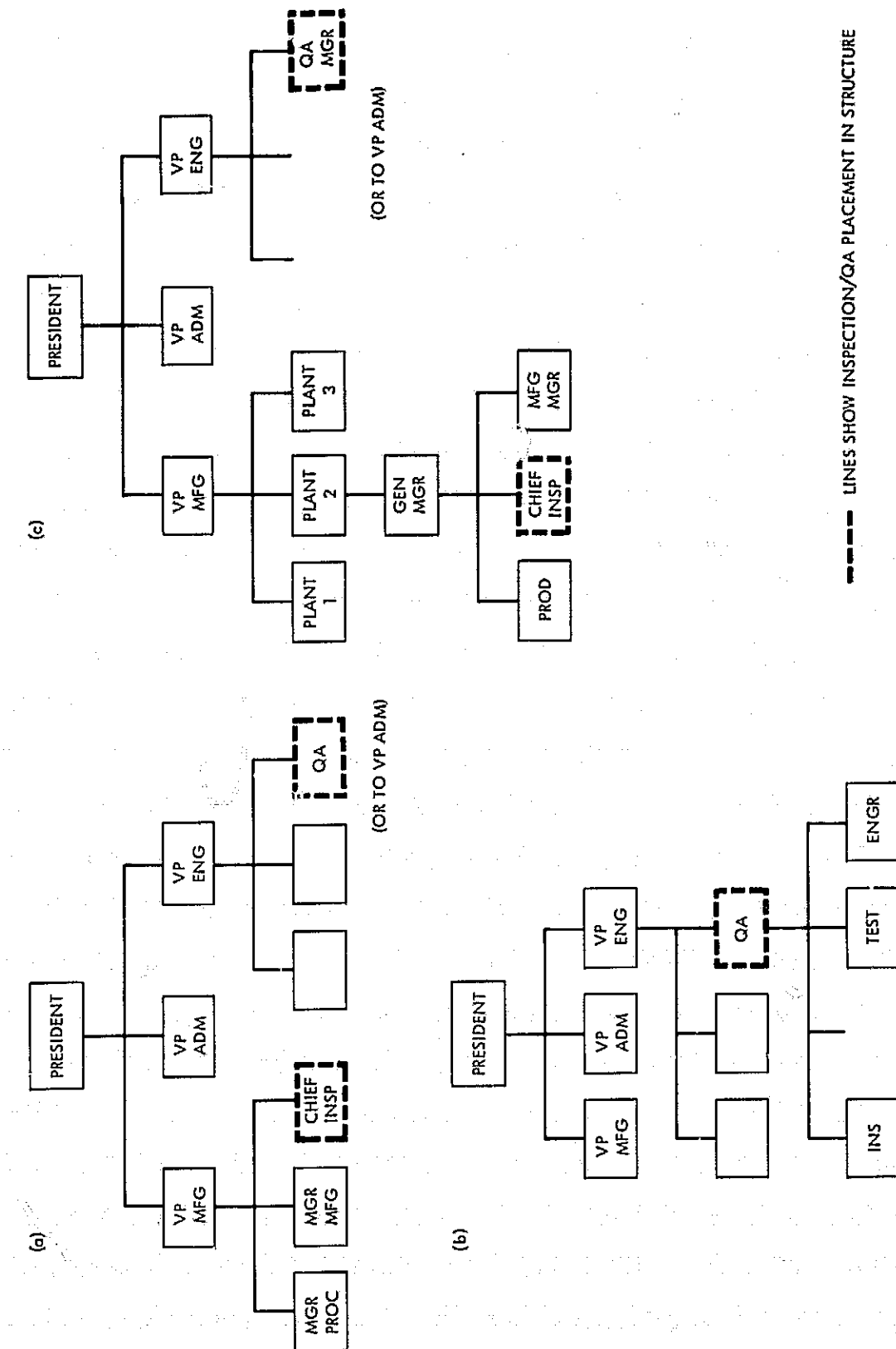


Figure 1. Typical Organization Structures (Acceptable)

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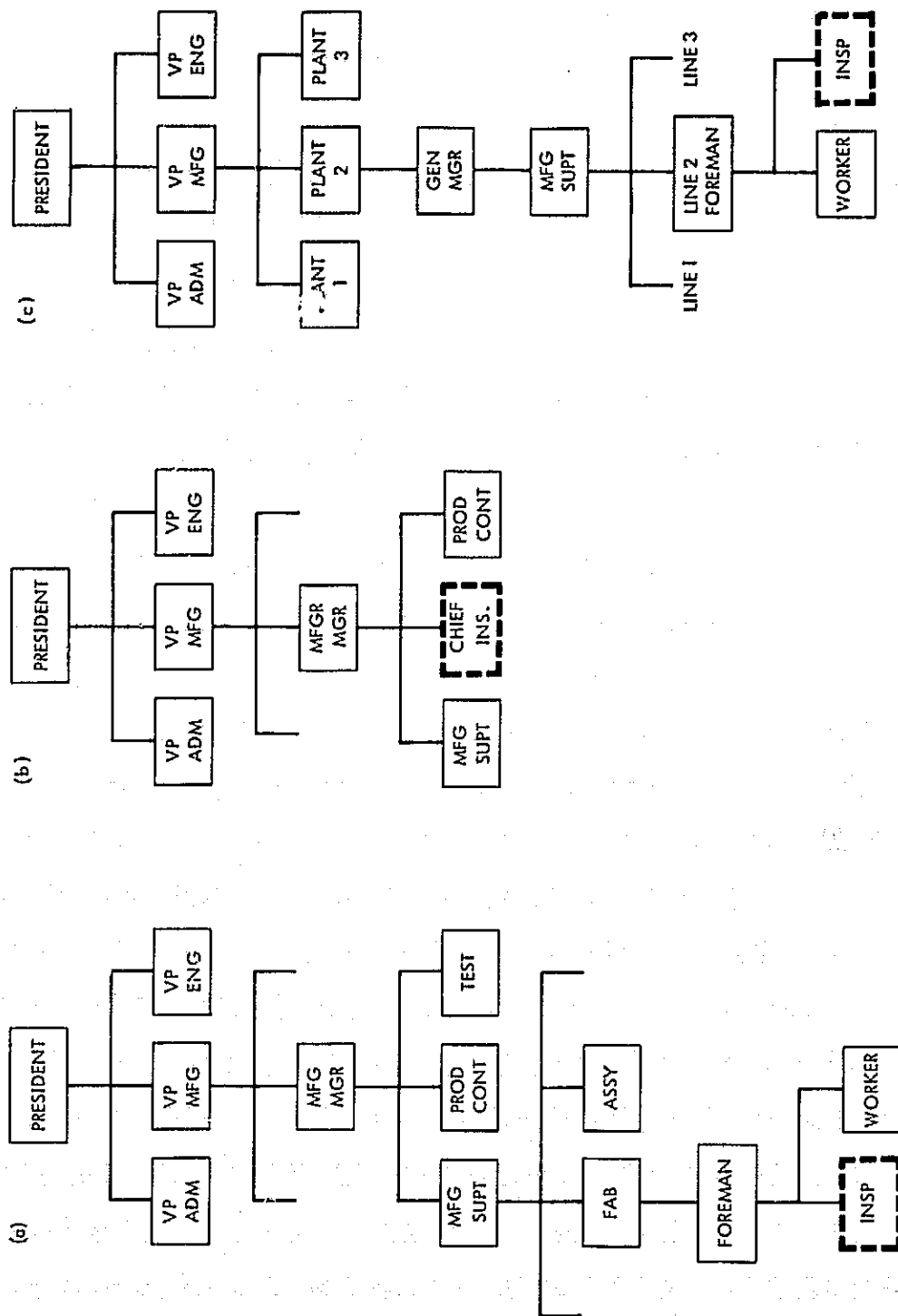


Figure 2. Typical Organization Structures (Non-Acceptable)

4.0 DESIGN AND DEVELOPMENT

4.1 DESIGN DOCUMENTATION

The producer shall prepare and maintain design definition documents which:

- (a) Describe features, characteristics, and criteria showing that the design complies to regulations, codes, standards, specifications and other buyer requirements.
- (b) Identifies and sets tolerances for those characteristics necessary to purchase, fabricate, assemble, inspect, test, install on-site and checkout hardware.
- (c) Define the complete configuration of the vehicle and/or subsystem, as-designed.

Since the emphasis of the quality assurance program is on the important (including aesthetics) and critical aspects of the design, and the concept of "doing it right the first time", assistance of the designer is needed in order to achieve this. Characteristics essential to the installation, function or performance of hardware shall be uniquely identified to determine the depth and frequency of inspection or test. When some critical characteristics are repetitive throughout many different drawings (e.g., a closely held toleranced dimension, torquing to a particular level or of a particular type of fastener, particular applied circuitry, etc.), these may be called out in a standard document and the drawing may contain an identifier or note as being "*Critical*" or containing a "*critical parameter or item*". These include but are not limited to characteristics which:

- (a) Affect safety, reliability, or vehicle operation
- (b) Implement the requirements of applicable federal, state, or local codes
- (c) Affect features specified by the buyer

4.2 DESIGN ANALYSES AND ENGINEERING STUDIES

Design analyses and engineering studies, conducted to satisfy design, system safety, reliability and maintainability requirements, shall be reviewed to provide a basis for the conduct of quality program functions. Identification of hazards, single failure points, redundant elements, and failure modes shall be used for:

- (a) Adjusting the scope and depth of quality program activities
- (b) Establishing mandatory inspection points, quality standards and accept/reject criteria, and
- (c) Establishing the test program to qualify new hardware and demonstrate that production hardware meets requirements.

4.3 STANDARD PRACTICES

Producer activities to standardize design and manufacturing practices to promote productivity and cost effectiveness shall be extended to quality program functions. Producer standard practices and documents shall be established for:

- Fabrication and assembly methods
- Process specifications and standards

- Selection and identification of mandatory inspection/tests
- Inspection and test methods and procedures
- Accept/reject criteria, including workmanship
- Repair, rework and modification procedures

4.4 PARTS, MATERIALS, AND PROCESSES

The producer shall control the selection, specification, and application of parts, materials and processes to ensure that:

- (a) They satisfy contract and design requirements under the specified conditions, including qualification, as applicable
- (b) Consideration has been made of safety-related or failure-avoidance features such as flammability, toxicity, pollution, compatibility of materials, materials with fluids, and resistance to fracture or stress corrosion
- (c) Those essential to safe, reliable and economical transit system operations are described on specification control drawings which define essential features for competitive procurement, processing, inspection and testing
- (d) Substitutions for previously qualified hardware are qualified by analysis and test prior to use in production hardware
- (e) Use is made of in-house failure and problem experience, and of data, when available, from industry associations.

4.5 DESIGN REVIEWS-NEW DESIGNS, MAJOR CHANGES TO EXISTING DESIGNS

Designs for each contract shall be reviewed to ensure accomplishment of unique contract requirements and selected options, using experience data of producer, buyer and transit industry. Quality Assurance personnel shall participate in such reviews to:

- (a) Promote manufacturable, repairable and inspectable designs
- (b) Facilitate planning for fabrication, inspection and test
- (c) Identify needed accept/reject criteria not on or referenced by engineering drawings
- (d) Identify ambiguities or deficiencies in design documents whose correction is necessary to properly perform quality program functions while producing conforming hardware

4.6 CONTRACT REQUIREMENTS REVIEW

Quality Assurance personnel shall participate in detailed reviews of contractual requirements for vehicles and subsystems, the object of which is to ensure that:

- (a) The design and fabrication processes presently selected and documented will satisfy all buyer options. Any additional design and fabrication features shall be documented in a timely manner to satisfy technical requirements within the required delivery schedule;

- (b) A list of buyer options or features different from standard production hardware is prepared for use in planning design, fabrication, assembly inspection and test; and in procurement activity.

4.7 DESIGN VERIFICATION

Unverified new designs, for complete vehicles or major portions thereof including revisions and upgrades, shall be verified by qualification test and inspection of the prototype prior to release for production. Prototype fabrication, assembly, inspection, and test activities and results shall be factored into the production design, manufacturing, and test documentation, tooling, and activities.

5.0 PROCUREMENT CONTROL

5.1 PROCUREMENT DOCUMENT CONTENT

Procurement documents shall contain technical performance and quality assurance requirements to satisfy design and fabrication (including assembly) criteria. Procurement documents for major assemblies; qualified parts, materials, components, assemblies; and hardware critical to safety, reliability, and operation shall be reviewed prior to release to ensure that quality requirements are proper and appropriate to the hardware being procured and to its usage.

As part of the procurement requirements, the contractor shall pass on all contractual and specification requirements levied on him to his suppliers, as appropriate to the hardware being procured.

5.1.1 TECHNICAL REQUIREMENTS

Technical requirements shall define or identify functional, physical and chemical, material features and/or characteristics. Applicable regulations, codes, specifications or standards which describe or limit characteristics shall be referenced, or included by reference in the cited manufacturer's documents. Manufacturing documents and/or engineering drawings (e.g., spec. control dwg.) cited in purchase orders/procurements shall be provided to the supplier.

5.1.2 QUALITY ASSURANCE REQUIREMENTS

Quality Assurance requirements shall be selected that are pertinent to the nature of the hardware purchased and its criticality to safe, reliable, and economical transit system operations.

- (a) Suppliers of major subsystems for rail or guideway vehicles and automatic train controls or for new designs for buses shall have a quality program meeting all, or cited, portions of this document.
- (b) Suppliers of other hardware shall have a quality program meeting the requirements of ANSI std. Z1.8, or an existing supplier-generated equivalent quality system.
- (c) Special or unique inspections or tests required to be performed by the supplier shall be identified.
- (d) Inspection and test data to be provided with shipments of hardware shall be defined.
- (e) Requirements to identify inspection and test data with particular hardware delivered shall be defined (e.g., use of serial, lot or heat numbers), as well as requirements for identification to be provided on the hardware or attached papers (e.g., part number and serial, lot or heat number, as applicable).

- (f) For hardware essential to safe, reliable and economical transit system operations, the type of inspections and tests to be performed by the purchasing activity (e.g., vehicle producer) at source shall be defined. Provisions shall be included to provide purchaser's access to the supplier's plant, equipment and records to enable inspection and test by the purchasing activity. In addition, proviso shall also be made for allowing visits and/or inspections by the purchaser's customer or their designees.
- (g) For castings, forgings, printed circuit boards, complex items, high-cost items, and safety-related components, provisions shall be made for first article inspection and periodic audit of the supplier's quality program/inspection system.
- (h) When hardware essential to safe and reliable transit system operations is purchased to supplier's catalog number or description, the supplier shall be required to:
 - (1) Provide evidence that the hardware supplied is identical to that previously approved by the purchaser or previously qualified
 - (2) Provide evidence that materials, parts and processes are the same as used in the unit which was previously approved by the purchaser or previously qualified by test
 - (3) Submit to the purchaser changes and substitutions from that previously qualified by test or approved by the purchaser for his approval prior to their implementation.
- (i) Require that failure and nonconformance information development during supplier qualification test or final test be provided to the purchasing activity. The supplier will have available records of all lower level test failures and nonconformances.

5.2 SUPPLIER SELECTION

Suppliers shall be selected and evaluated on the basis of:

- (a) Previous and continuous record of supplying hardware of required quality and of the type being procured, or
- (b) A pre-award survey at the supplier's facility to evaluate his quality system, current capability to produce hardware as required, quality history for related hardware, and his record in correcting deficiencies on similar hardware reported by other producers or by transit properties. In lieu of conducting his own pre-award survey, the producer may use an available or existing pool of supplier survey information, if that survey criteria is similar to requirements for the purchase involved.
- (c) When hardware purchased to supplier's catalog number or description is essential to safe and reliable transit system operations, the suppliers are required to be evaluated by a pre-award survey made by the purchaser or from an existing pool or supplier survey information, and shall have a previous and continuous record of supplying hardware of required quality and of the type being procured.

When hardware is required to meet qualification requirements, suppliers shall be limited to those currently producing; willing to produce hardware identical to that previously qualified by test by that supplier; or willing to qualify his design.

5.3 SOURCE INSPECTION AND EVALUATION

Source inspection and/or inspection system evaluation shall be accomplished by purchaser's representatives at the supplier's plant when:

- (a) Characteristics and features identified as essential to safety, reliability, or operation are not inspectable or testable after receipt, or are not economical to inspect or test after receipt.
- (b) The supplier's quality program or inspection system is suspected of causing poor product quality, or when the supplier provides complex, high-value or critical hardware.

Source inspection and evaluation will include: inspecting hardware; witnessing critical fabrication and assembly operations and tests; and evaluating those elements of the quality program or inspection system when they are suspected or permitting insufficient quality. The supplier's quality program/inspection system shall be evaluated periodically whether or not source inspection is established at the supplier's plant to ensure that all elements operate satisfactorily during the course of the subcontract. Purchaser's representatives will perform or witness first article inspection for:

- (a) Hi-value or safety-related hardware
- (b) Hardware produced by special tooling, automated machine tools or by special fabrication processes, and
- (c) Hardware fabricated to vehicle producer's designs.

Inspection at source should be at the highest level of assembly at which the essential characteristics or features are accessible for inspection. The purchasing activity should inspect additional characteristics and features and increase the depth and frequency of inspection if the supplier's product quality history is less than required.

5.4 RECEIVING INSPECTION

The contractor shall perform receiving inspection which:

- (a) Controls receipt of purchased hardware and materials and reviews inspection and test data provided by supplier inspection and by source inspection to verify that satisfactory data and identification are provided
- (b) Identifies the important hardware for which inspection/test upon receipt is necessary to assure overall cost effectiveness or proper function of the delivered end-item.

- (c) Uses inspection checklists and purchase order information which identify characteristics and accept/reject criteria for hardware to be inspected upon receipt. Unless the necessary inspection criteria are shown on engineering drawings in a manner suitable for ready use by inspectors, such checklists shall be prepared for:
 - (1) Functional, critical, hi-value or safety-related hardware
 - (2) Hardware purchased by supplier's catalog number or description
 - (3) Hardware fabricated to vehicle producer's design or tooling.
- (d) Verifies by inspection and test those critical characteristics identified on engineering drawings or inspection checklists as being essential to safe, reliable and economical transit system operation. Such verification is not mandatory if those critical characteristics were verified at source and acceptable evidence of such is on hand. Hardware purchased by supplier's catalog number or description shall be inspected/tested for essential functions and interface characteristics, unless these were verified by source inspection, and acceptable evidence is on hand.
- (e) Verifies by sampling inspection other characteristics identified on engineering drawings, specifications, inspection checklists or purchase descriptions. Physical characteristics previously verified at source (that do not require dis-assembly or special test set-ups to verify) shall be periodically inspected again to verify that source inspection records continue to be valid evidence of quality conformance
- (f) Utilizes sampling inspection. It is to be performed against established sampling tables which provide for adjusting inspection to reduced, normal, or tightened inspection based on quality history. Such tables shall be extracted or prepared from established specifications for sampling (e.g., MIL-STD-105 or some other recognized statistical system) to establish an economic balance between producer and buyer's risk. AQL's (Acceptable Quality Level) shall be established for various classes or kinds of hardware, based on economic considerations and the criticality of the hardware to safe, reliable and economical transit system operation. Tightened inspection shall be used initially if no pre-award survey was made and no quality history is available for that type of hardware from that supplier
- (g) Segregates conforming from nonconforming hardware; the latter shall be returned to the supplier or arrangements made for supplier rework or repair. Conforming hardware shall be protected in storage and while moving between work stations to prevent damage or quality degradation
- (h) Provides nonconformance information to the supplier. Suppliers shall be required to advise action taken to remedy the nonconformance, prevent its occurrence on subsequent deliveries and to identify other deliveries suspected of having the same nonconformance
- (i) Verifies that the as-delivered configuration of safety-related, high-value or complex hardware agrees with requirements and supplier-provided documentation

- (j) Identifies and controls material or hardware which are subject to deterioration with age to assure their usage within the established useful life
- (k) When performed in plant areas other than the receiving inspection area, shall provide for nonconformance feedback to the receiving inspection vendor record system.

6.0 IDENTIFICATION AND DATA RETRIEVAL

6.1 IDENTIFICATION

Materials, parts, devices and assemblies shall be identified by unique part numbers to ensure:

- (a) Functional hardware and major assemblies can be related to fabrication, inspection, test and operating records
- (b) That all required buyer requirements and options are satisfied to produce hardware as ordered
- (c) Future repair parts and production reorders will be interchangeable (directly or as a replacement)
- (d) Support of failure reporting/analysis procedures and prevention of recurrence of defects
- (e) Ability to locate suspect hardware in vehicles or subsystems already processed or delivered
- (f) That all parts and hardware listed in parts catalogs, illustrated parts breakdown documents, etc. provided to the customer are identifiable.

Further detail identification methods (e.g., serial numbers, log numbers, heat numbers or date codes) shall be selected depending on the nature of the hardware and its criticality to safe, reliable and economical transit system operation. Serial numbers shall be applied to major functional replacement hardware and to that hardware which the transit system specifies for reasons of maintenance during operations.

Items due to their size, construction, use or design may have their identification on associated paperwork or accompanying tag.

6.2 DATA RETRIEVAL

A system for retrieving inspection and test data for serialized items, heat-treated items, or other items deemed necessary by the manufacturer shall be implemented. Also, when codes, standards, specifications, or the contract require traceability of hardware to fabrication, inspection, test, and processing records, such records shall be retrievable. Data retrieval methods shall:

- (a) Enable recall of receiving, inspection, and test records
- (b) Enable tracking or recording of open problems or nonconforming hardware and their disposition.

7.0 FABRICATION AND ASSEMBLY CONTROLS

7.1 GENERAL

The producer shall plan and conduct fabrication and assembly operations to ensure:

- (a) Use of standardized fabrication and assembly methods
- (b) The correct sequence of fabrication and assembly operations is employed, and that they are shown on a flow chart. Inspection and test operations are shown on the same flow chart
- (c) Characteristics identified on engineering drawings and essential interface features are built into the hardware and are not degraded by subsequent processing operations, including handling
- (d) Provision is made for fabrication and assembly of all buyer options or features which differ from standard production hardware
- (e) All requirements imposed by the buyer, including those relating to appearance, are accomplished prior to delivery of vehicles and subsystems
- (f) When out-of-position work is to be done, it is planned and properly sequenced
- (g) Only conforming parts, materials, devices or processes are used and substitutions are approved by the buyer, if particular buyer requirements are involved
- (h) Nonconforming hardware is removed from work operations
- (i) Manufacturing planning is used to define and control what is to be fabricated or assembled. It shall identify as a minimum the part number, drawing change letter, and quantity to be produced. It should specify, as a minimum: the sequence of operations, the tooling to be used, the work and processes to be performed, the inspection points, serial numbers or special features to be recorded, specific items to be verified, and inspection acceptance.
- (j) Shop travelers and records of processing accompany work and identify completion of operations and who performed the work, where manual skills are involved
- (k) Handling, storage and movement of hardware does not degrade its quality. Protective containers shall be used to preserve necessary cleanliness and avoid damage or loss of identification
- (l) Necessary controls of the work environment (e.g., shop cleanliness, temperature and humidity) are established and maintained consistent with achievement of required quality.

7.2 SPECIAL PROCESSES

Controls shall be established for special processing for fabrication operations such as welding, heat treating or plating, surface preparation bonding, painting, soldering, printed circuit board fabrication, and for nondestructive inspection operations such as radiography, ultrasonics, liquid penetrant and magnetic particle. Controls and their application to equipment, procedures, and operating and inspection personnel shall be defined. Special processes shall be identified with applicable regulations, codes, standards or specifications. Fabrication and inspection tooling, equipment and material qualified/certified for a special process shall be identified and used in the manner prescribed.

Operators making manual critical structural welds and inspectors of critical welds shall be certified and qualified by training and demonstration of continued competence. Certified personnel shall be given a card or badge to evidence currency of their certification. Work performed by persons not currently certified shall not be accepted. Personnel performing nondestructive inspection (e.g., radiography or liquid penetrant) shall be certified/qualified as required by the applicable regulation, code, standard or specification.

7.3 CONTROL OF TOOLING

7.3.1 INSPECTIONS PRIOR TO USE

Tooling such as jigs, fixtures, masks, casting molds, and dies and which control dimensions and contours shall be inspected first and then proven by first article inspection prior to production use. Such tooling shall be reinspected and repaired or replaced at appropriate intervals. Changes to tooling documents shall be controlled and reinspected. A record shall be maintained relating specific tooling to particular vehicle configurations.

7.3.2 AUTOMATED TOOLS AND THEIR SOFTWARE

Automated machine tools, numerical control tools, and process equipment controlled by computer output or tape/card/disc storage devices shall be proven by first article inspection. If such machine tools incorporate tooling which defines a contour or dimension, such tooling shall be inspected and controlled. Associated software (computer programs and related documents) and changes thereto shall be controlled to ensure correct software is used as specified and is not degraded in use. New software shall be debugged prior to use.

7.4 WORKMANSHIP STANDARDS

7.4.1. GENERAL

Work samples and pictorial or other visual aids shall be used to define features of acceptable workmanship where such features are not completely defined in design documents or inspection checklists. Examples are wire terminations, welding, runs of electric cables or fluid lines, and mounting parts on printed wiring boards. Workmanship standards shall show rejection criteria where such will promote proper workmanship.

7.4.2 APPEARANCE (COSMETIC) DEFECTS

Workmanship standards shall be established to define accept/reject criteria for appearance defects (e.g., paint; exposed rivet heads in careless or nonuniform order; dimples or wrinkles on sheet metal panels). Such standards should include appearance or aesthetic considerations which would be obvious to a transit rider. Appearance defects which are readily correctable (e.g., dirty

windows or grease smudges) while not necessarily shown on workmanship standards, are the producer's responsibility to correct. Special attention shall be given to those defects which may appear to be cosmetic, but in truth may affect structural integrity or vehicle durability.

7.5 OUT-OF-POSITION WORK

When fabrication and assembly processing must proceed despite shortage of parts or subassemblies, the missing hardware shall be documented, and planning and arrangements initiated to ensure that work to be accomplished out-of-position is controlled to the same degree as normal work. Out-of-position work shall be accomplished to established workmanship standards and accept/reject criteria.

8.0 INSPECTION AND TEST

8.1 GENERAL

The producer shall plan and conduct an inspection and test program to qualify new designs or prototype hardware, and to verify that production hardware satisfies his own requirements as well as applicable regulations, codes, standards, specifications and buyer-specified requirements.

8.2 QUALIFICATION OF NEW DESIGNS

The producer shall demonstrate that the design, as documented, meets specified requirements by qualification test of a prototype vehicle and/or subsystem. The qualification tests shall be planned and conducted to demonstrate that prototype hardware, fabricated using materials and processes intended for production hardware, meets performance requirements and has adequate design margins for safety under the most adverse design conditions. Also, such tests shall identify problems and failure modes, so that they may be eliminated, or minimized where elimination is not practical. The design shall be modified as determined by results of qualification testing. Retest after modification shall be sufficient to demonstrate qualification of the vehicle and/or subsystem.

8.3 PLANNING

The quality program shall provide inspection and test planning so that:

- (a) Design definition documents and the contract are reviewed to ensure that identified features/characteristics are inspected and tested to the necessary degree, e.g.
 - Features and characteristics identified as essential to safety, reliability and operation shall be physically verified for conformance on each and every unit of hardware.
 - Other features and characteristics shall be verified to the degree necessary to satisfy manufacturer and contract requirements.
 - Experience of producer and transit system defect and failure history shall be used in establishing and adjusting inspection and test activities.
- (b) Failure mode and effects analysis and other design analysis which identify and study potential failures are reviewed and considered in selecting inspection points, mandatory inspections and determining the kind, depth and frequency of inspection and test.
- (c) Inspection and test results shall be recorded. Hardware shall be accepted prior to moving the work to the next point unless authorized by approved "out-of-position" planning.
- (d) Features required by the buyer, including those affecting appearance, shall be producer inspected and tested, prior to buyer inspection and test.

- (e) Inspections are performed and documented prior to subassembly or module close-up, which would prevent required inspections.
- (f) The sequence and type of inspections and tests have been selected to ensure that manufacturer and contract requirements have been fulfilled.
- (g) Inspection and test work stations are compatible with fabrication and assembly operations.
- (h) Adequate time is included in production schedules for necessary inspections and tests.
- (i) Appropriate instruments and other measuring equipment are available at the work station at the time needed.
- (j) Provisions are included for specific inspection points required by the buyer. Buyer inspection and test results may be identified and recorded on the producer's records. Hold points for buyer inspection and test shall be indicated on producer's flow charts and inspection and test planning documents.

The above shall be applied as appropriate to inspection and test at all levels of processing and assembly, including source, receiving, in-process, final and end-item.

8.4 INSPECTION AND TEST CRITERIA

8.4.1 DOCUMENTS-GENERAL

The latest, correct and applicable documents used in inspections and tests shall be available at the inspection/test station. Pertinent copies shall be provided to patrol inspectors. Such documents shall include, as appropriate, inspection checklists, inspection and test procedures, and engineering drawings or planning papers which identify characteristics to be inspected and tested.

8.4.2 INSPECTION CHECKLISTS

Inspection checklists shall be prepared to define what to inspect and to identify accept/reject criteria when engineering drawings or other documents are not suitably detailed or available, and will be available at the place of inspection for use by the inspector. If inspection stations are utilized, inspection checklists apropos to that station shall be utilized.

Unusually complex inspection operations and those classed as special processes (e.g., radiography, ultrasonic or other NDI — Non-Destructive Inspection — method) shall be documented by written inspection procedures of the same general scope as in paragraph 8.4.3.

8.4.3 TEST PROCEDURES

Written test procedures shall be used. These procedures shall:

- (a) Identify hardware involved
- (b) Identify features and characteristics, and other design criteria including parameters to be tested or inspected

- (c) Include or reference applicable accept/reject criteria, including workmanship standards
- (d) Identify inspection, measuring and test equipment
- (e) Include established test methods or detail procedures and precautions to be observed
- (f) Show interconnections of hardware and measuring equipment
- (g) Define or identify prerequisites to be accomplished prior to test (e.g., test readiness inspection before system test)
- (h) Define environments to be maintained during inspection and test
- (i) Define actions to be taken when nonconformance or failure occur, including conditions for resuming or repeating test
- (j) Identify hazards to hardware or personnel and applicable precautions to comply with established safety regulations and requirements to ensure personnel safety and prevent damage to hardware or test equipment

8.4.4 ACCEPT/REJECT CRITERIA

Accept/reject criteria for inspections and tests shall be assembled and made available at the place of inspection or test. Such criteria may be shown on, or extracted from:

- Buyer requirements specified in a given contract
- Engineering drawings
- Government documents
- Hardware specifications and standards
- Industry codes and standards
- Inspection checklists
- Inspection procedures (unusually complex operations only)
- Planning papers
- Process specifications and standards
- Test procedures
- Workmanship standards.

8.5 INSPECTION

8.5.1 GENERAL

The producer shall demonstrate that production hardware conforms to specified requirements prior to delivery by a planned sequence of inspections and tests. These shall be performed in-process and at various assembly levels to demonstrate that the hardware produced:

- (a) Has all of the features and characteristics as required in design definition documents
- (b) Is of the required configuration
- (c) Satisfies all manufacturer and buyer-specified requirements
- (d) Is assembled and installed so that the overall transit system can operate as specified
- (e) Has authorized rework and that the repair meets specified standards

Inspectors shall use inspection criteria established for the inspection station or hardware involved.

8.5.2 FIRST ARTICLE INSPECTION

First article inspections shall be performed to verify that a production process is set up and arranged to produce conforming hardware and to verify that the controlling documents for that process are appropriate for the hardware as intended. First article inspection by the producer shall be mandatory for:

- (a) High-value or safety-related hardware
- (b) Hardware produced by special tooling, new tooling, computer/numerically controlled tools or by special fabrication processes
- (c) First item produced by tooling, jigs, fixtures, etc.

First article inspection may be performed by the buyer at higher levels of assembly to:

- (a) Verify that hardware is produced as intended when the contract specifications were prepared, and
- (b) Promote complete understanding between vehicle producer and the transit system buyer.

Buyer first article inspection usually will be mandatory during fabrication, assembly and test of the first end-item.

8.5.3 IN-PROCESS INSPECTION

In-process inspection, including detail parts, subassemblies, and assemblies, may be performed by patrol (random) inspection and at fixed inspection stations. Patrol inspection will be performed on a random basis using inspection checklists. Required inspections shall be performed at the highest level of assembly before the required characteristic becomes inaccessible due to assembly/module closeup or further operations. Hardware, such as parts/subassemblies, shall as a minimum receive a final inspection before moving to stock, storage, or to the next assembly operation or processing point. Results of in-process inspections and unresolved or open nonconformances shall be reviewed at inspection stations and be available to patrol inspectors in order to determine and arrange for necessary changes, dispositions, and corrective actions to be accomplished before moving hardware.

A list of shortages, missing parts, subassemblies, etc, and unresolved discrepancies or nonconformances shall be prepared and maintained. This may be facilitated by keeping such records and shop-travellers with the hardware concerned. Each item on the list shall be periodically reviewed to:

- (a) Determine its impact on remaining planned inspections and tests
- (b) Expedite completion of assembly and resolution of nonconformances
- (c) Initiate revisions of sequence of planning inspections and tests and arrange for out-of-position accomplishment, if necessary

8.5.4 END-ITEM INSPECTION

All hardware to be delivered shall undergo end-item inspection prior to final functional test. End-item inspection shall verify that required evidence of satisfactory completion of prior inspections and tests is on hand and that safety-related components and all buyer-specified options are installed as required. Prior to shipment, an inspection shall be performed to verify that hardware attributes and configuration conform to that specified or approved for the contract. Rail/guideway vehicles and automatic train control equipment shall also receive another end-item inspection upon assembly of the complete system as installed at the transit property.

8.6 FUNCTIONAL TEST

Hardware shall be functionally tested during fabrication and assembly buildup to the extent defined by the manufacturer and provided in the contract. Typically, functional testing will occur at the following levels of assembly:

- (a) Module levels (e.g., turn signal, printed circuit card);
- (b) Assembly levels (e.g., computer: storage/memory; rail/guideway: wiring);
- (c) Subsystems (e.g., rail/guideway: door operation; bus: engine; train control: computer)
- (d) System (e.g., Bus; ATC; rail vehicle)

Functionally tests shall not proceed until prior inspection appropriate to that stage of assembly has been completed. Shortages and nonconformances which would impact or invalidate a functional test shall be corrected before start of the functional test involved. Test specifications shall be prepared for functional tests at the subsystem and system levels to define the tests, their sequence and applicable procedures, including safety precautions and shut-down. For rail and guideway vehicles and automatic train control systems, functional tests shall be made at the producer's plant prior to shipment of subsystems and vehicles, and the complete system shall be functionally tested as installed at the transit property.

8.7 OUT-OF-POSITION INSPECTION/TEST

When fabrication and assembly processing must proceed despite shortage of parts or subassemblies, the out-of-station or out-of-sequence work shall be inspected and tested as specified for normal operations.

8.8 HARDWARE QUALITY AUDITS

Hardware at various assembly levels shall be independently reinspected and retested on a sample basis to verify its quality. The sample sizes and intervals between audits shall be based on the criticality of the hardware, whether it is safety-related hardware, quality history and nonconformance studies.

8.9 INSPECTION AND TEST RECORDS

Records shall be maintained of inspections and tests showing what was accomplished, observed and results, dates and responsible individual or activity. Any rework, repair or modification occurring during, or as the result of, inspection/test shall be documented. Records shall be complete, accurate and traceable to the particular hardware involved during operations at the producer's plant. Inspection and test checklists may be used as inspection and test records. Records for a particular vehicle or subsystem shall be collected and show:

- (a) Satisfactory accomplishment of required inspections and tests before shipment
- (b) Shortages of parts, subassemblies, etc.
- (c) Unresolved discrepancies or nonconformances.

Final inspection and test records, and a list of buyer-authorized waivers or shortages shall be forwarded to the buyer with each vehicle or subsystem shipment as specified in the contract. For rail or guideway vehicles and automatic train control systems, final inspection and acceptance test data of the complete transit system as installed shall be provided to the transit property upon their completion, and all other inspection and test records will be kept available in the manufacturer's plant.

8.10 WAIVERS

If shortages and nonconformances are minimal, permission of the buyer shall be obtained prior to shipment with shortages or unresolved nonconformances. The buyer shall be provided a copy of each shortage or nonconformance and advised of the nature and impact on contract compliance.

9.0 NONCONFORMING HARDWARE

9.1 GENERAL

Hardware that does not conform to established requirements shall be identified as nonconforming, segregated, and removed from work operations to prevent its use unless specifically authorized. Hardware which can become conforming by completion of documented procedures may be returned to work operations after concurrence of authorized fabrication and inspection personnel for completion, and then reinspected and tested (as apropos).

Hardware containing safety-related or functional defects, or not meeting customer requirements shall not be repaired (varies from the design requirement) or used "as is" prior to the purchaser's approval of the repair, or purchaser's waiver of that requirement prior to implementation of the disposition. Requests for such waivers shall include an engineering evaluation by the seller of the effect of the nonconformance upon specified requirements.

Nonfunctional defects and aesthetic/cosmetic defects (nonconformances affecting only appearance) may be accepted at "producer's risk" if authorized inspection and fabrication personnel concur. "Missing or short" parts, subassemblies, etc., shall be treated as nonconformances. This is to ensure that the effect of their missing at scheduled time of installation does not adversely affect subsequent operations, and that they are properly incorporated and inspected prior to end-item completion and delivery.

Nonconforming hardware shall be reinspected after repair or rework. If the hardware is functional in nature, a retest or penalty test shall be conducted to reverify its acceptability subsequent to the repair/rework.

9.2 DOCUMENTATION

9.2.1 CONTENTS

Documentation shall include:

- (a) Identification and part number of hardware involved
- (b) Inspection or test point where nonconformances were detected
- (c) Sufficient details describing the nonconformance to facilitate disposition, and reinspection
- (d) Disposition of the nonconforming articles
- (e) Rework or repair instructions
- (f) Indication of reinspection after repair or rework
- (g) Corrective action for: repetitive nonconformances; nonconformance dispositions requiring approval or concurrence from the customer

9.2.2 DOCUMENT DISTRIBUTION

Remedial and preventive actions usually require some action by various organizations in addition to those performing quality program functions. All affected organizations shall receive copies of nonconformance documents.

10.0 CORRECTIVE ACTION

10.1 GENERAL

Corrective action involves both remedial and preventive actions.

Conditions adverse to quality (nonconformances, problems and unsatisfactory conditions) shall be identified promptly, corrected and action taken to prevent recurrence. If preventive action cannot be determined from analysis or review of conditions, drawings and documents involved, laboratory analysis of failed hardware is required. Remedial action means repair or rework of the hardware and software involved, including all units already fabricated.

10.2 SAFETY-RELATED HARDWARE

Nonconformances involving defects affecting safe operation and/or use of safety-related hardware shall receive priority attention in determining their basic causes and in developing effective preventive action. Remedial and preventive action proposed shall be reviewed by designated supervisory/managerial personnel prior to disposition and prior to action to prevent recurrence. Such reviews shall determine the adequacy of actions proposed. Each priority nonconformance shall be assigned to a responsible individual for follow-up until that matter is closed by supervisory/managerial concurrence of the adequacy of actions taken.

10.3 CLOSEOUT OF NONCONFORMANCES

Nonconformances shall be considered open until remedial and preventive actions have been completed and verified by reinspection or retest. If the corrective action involves a change to documents or software, the nonconformance shall remain open until the pertinent documents or software have been modified as required.

10.4 TRANSIT PROPERTY FEEDBACK

The producer's corrective action should focus on early and prompt detection of unsatisfactory quality and potential problems. The manufacturer shall initiate corrective and preventive action to prohibit the continuation of the type of failures or problems reported by the transit properties.

11.0 INTERNAL QUALITY PROGRAM AUDITS

Functions, activities, methods and procedures of the quality program shall be evaluated periodically or audited by experienced producer personnel not responsible for them. Such quality program audits may be conducted in conjunction with hardware quality audits, particularly when the latter reveals poor quality or trends toward poor quality. Audits should determine compliance with established policies and procedures and their effectiveness in maintaining or improving hardware quality.

Results of audits shall be documented and distributed to concerned supervisors and managers. Responsibility for corrective action in response to audit findings and recommendations shall be assigned and progress tracked until management considers the corrective action adequate and cost-effective.

12.0 CALIBRATION AND METROLOGY

The producer shall select, use, calibrate, adjust and maintain measuring and test equipment to provide valid measurements and tests consistent with the accuracy required. Records shall be maintained of calibration dates and results of calibration. Equipment shall be marked with due date of next calibration to ensure that inspection and tests are performed with calibrated equipment as necessary. Intervals of calibration shall be periodically reviewed and adjusted depending on equipment use, accuracy, required precision, and adjustment and maintenance experience. Tooling used as a media for inspection or which controls dimensions or contours shall be subject to the requirements of this paragraph. Instruments used for indication only need not be calibrated. Calibration shall be traceable to National Bureau of Standards.

13.0 INSPECTION AND TEST STATUS IDENTIFICATION

The producer shall establish and maintain controlled methods to indicate the inspection and test status of hardware so that its acceptability is known during all phases of contract operations. Methods shall be included to identify nonconforming hardware in a manner to prevent its use. Stamps, tags, stencils and other indicators of conformance shall be issued only to authorized and qualified personnel.

14.0 HANDLING, MARKING, SHIPPING, AND STORAGE

The producer shall establish and maintain controls over the handling, shipping and storage of hardware, including cleaning, packaging and preservation as necessary to prevent damage, deterioration or loss. Special handling tools, tote boxes and other equipment shall be provided as appropriate. Marking and labeling methods shall be controlled to ensure use as intended, including ability to readily and safely repair hardware in transit system operations. Replaceable parts shall be marked with applicable part numbers, or if this is impracticable, the part numbers shall be shown on accompanying tags or papers.